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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/586,899

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Mads Eskelund Bjornvad

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EXAMINER

SINGH, SATYENDRA K

ART UNIT

PAPER NUMBER

1657

MAIL DATE

DELIVERY MODE

03/03/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/586,899	Applicant(s) BJORNVAD, MAD S ESKE LUND	
	Examiner SATYENDRA K. SINGH	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-29 and 32-44 is/are pending in the application.
- 4a) Of the above claim(s) 23-29, 39, 40 and 42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32-38, 41, 43 and 44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/21/06; 8/15/08</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's response and amendment to claims filed on 01/08/2009 is duly acknowledged.

Claims 23-29 and 32-44 (newly added) are currently pending in this application. Claims 1-22 and 30-31 have been canceled by applicant's amendments.

Election/Restrictions

Applicant's election **with traverse of Group II** (claims 32-42; drawn to a method for testing a host cell or screening a library of host cells for expression of an enzyme of interest; elected specie for "enzyme of interest" being **glucoamylase** and "enzyme capable of producing hydrogen peroxide" being **glucose oxidase**) in the reply filed on 01/08/09 is acknowledged. However, applicant did not distinctly and specifically point out the supposed errors in the restriction requirement and/or reasons for said traversal (see response, page 7, in particular). Applicants identify claims 32-38, 41 and 43-44 readable on the elected species. Claims 23-29, 39, 40 and 42 are therefore withdrawn from further consideration as being non-elected inventions.

The requirement, as set forth in the previous office action, is still deemed proper and is therefore made FINAL.

Claims **32-38, 41, 43 and 44** (as currently amended) are examined on their merits for the **elected specie** of enzymes (as discussed above) in this office action.

Minor Claim Informalities

Claim 34 recites "The method according to **any of claim 32**, wherein....present", which is inappropriate. Appropriate correction is requested.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 41 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim recites the limitation “*wherein the enzyme of interest is an enzyme for which a product of the chemical reaction between the enzyme of interest and a first substrate is hydrogen peroxide*”, which is confusing. The enzyme of interest such as glucoamylase, and the first substrate such as maltose (see instant disclosure, page 25, example 1, in particular) give rise to a product which is glucose that is further acted upon by one of the “other enzymes” such as glucose oxidase to produce hydrogen peroxide. Thus, given the disclosure, it is not clear as to what exactly is encompassed by the instant claim 41 as currently presented by applicants. Appropriate correction/explanation is required.

2. Claim 35 recites the limitation “**the polymer**” in line 1 of the claim. There is insufficient antecedent basis for this limitation in the broader claim 32.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 32, 33, 35-38, 41, 43 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuek & Kidby (1984; [U]).

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Claims are drawn to a method for testing a host cell or screening a library of host cells for expression of an enzyme of interest (elected specie, glucoamylase), wherein the method comprises cultivating a host cell expressing the enzyme of interest or a library of host cells expressing a library of polypeptides on or in a solid media in the presence of a first substrate, one or more other enzymes and a first dye, wherein a product of the chemical reaction between the enzyme of interest and the first substrate is a substrate for one of the other enzymes, and wherein the first dye is a substrate for one of the other enzymes, and wherein the product of the chemical reaction between the first dye and one of the other enzymes is a second dye, and wherein the color of the first dye is different from the color of the second dye and measuring the color of the second dye. (see limitations of instant claims 33, 35-38, 41, 43 and 44, in particular)

Kuek & Kidby [U] disclose a method for testing a host cell (or screening a library of host cells, such as screening fungi; see title, summary, and materials & methods, in particular) for expression of an enzyme of interest (such as glucoamylase), wherein the method comprises cultivating a host cell expressing glucoamylase (or a library of host cells expressing a library of polypeptides; see screening of fungal conidia, Materials & methods, in particular) on or in a solid media (see page 563, "selection of colonies on BSA", buffered starch agar plate screening, in particular) in the presence of a first substrate (i.e. starch), one or more other enzymes (contained in conidial cells; claims do not require isolated, extraneously added enzymes) and a first dye (starch-agar taken as the first dye that helps identify hydrolytic clear zones on plates), wherein a product (i.e. the "residual glucose" or dextrose; see page 563, 3rd paragraph, in particular) of the chemical reaction between the glucoamylase and the first substrate is a substrate for one of the other enzymes (such as glucose oxidase that produces hydrogen peroxide; see "Assay of residual glucose", in particular), and wherein the first dye is a substrate for one of the other enzymes (see section "Assay of residual glucose" uses a commercial diagnostic kit from Sigma Chemicals having glucose oxidase, peroxidase and a chromogen; see also page 564), and wherein the product of the chemical reaction between the first dye and one of the other enzymes is a second

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dye (i.e. a colored chromogen product having a denser color; claims do not require the identity of the dye compound), and wherein the color of the first dye is different (see also instant disclosure at page 19, wherein the first dye can be colorless) from the color of the second dye, and measuring the color of the second dye (measured at 450 nm wavelength; see pages 563-564); wherein the polymer is starch; and wherein the other enzymes comprise a peroxidase, and further comprise glucose oxidase that is capable of producing hydrogen peroxide.

2. Claims 32-38, 41, 43 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Horwath (US 4,882,273; [A]).

Claims are directed to a method for testing a host cell or screening a library of host cells for expression of an enzyme of interest (elected specie, **glucoamylase**), wherein the method comprises cultivating a host cell expressing the enzyme of interest or a library of host cells expressing a library of polypeptides on or in a solid media in the presence of a first substrate, one or more other enzymes and a first dye, wherein a product of the chemical reaction between the enzyme of interest and the first substrate is a substrate for one of the other enzymes, and wherein the first dye is a substrate for one of the other enzymes, and wherein the product of the chemical reaction between the first dye and one of the other enzymes is a second dye, and wherein the color of the first dye is different from the color of the second dye and measuring the color of the second dye.(see limitations of claims 33-38, 41, 43 and 44, in particular)

Horwath [A] discloses a method for testing a host cell (or screening a library of host cells; see title, abstract, examples 1-2 and claims, in particular) for expression of an enzyme of interest (elected specie, glucoamylase), wherein the method comprises cultivating a host cell (such as *Aspergillus niger* cells) expressing the enzyme of interest (or a library of host cells expressing a library of polypeptides) such as glucoamylase, on or in a solid media (such as starch-agar plates) in the presence of a first substrate (such as soluble Lintner starch; see examples 1 and 2, in particular), one or more other enzymes (such as horseradish peroxidase, HRP and glucose oxidase) and a first dye (such as ABTS or KI), wherein a product (such as

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glucose) of the chemical reaction between the enzyme of interest and the first substrate is a substrate for one of the other enzymes (such as glucose oxidase and peroxidase), and wherein the first dye is a substrate for one of the other enzymes, and wherein the product of the chemical reaction between the first dye and one of the other enzymes is a second dye, and wherein the color of the first dye is different from the color of the second dye (see column 6, example 1, second dye produces a zone of purple color indicating glucoamylase producing colonies), and measuring the color of the second dye such as visually as well as quantitatively (see column 5, in particular); wherein a polymer such as starch or agar is also present, which is capable of binding (type and extent of binding not specified in the claim; see instant disclosure, page 4, 2nd paragraph, in particular, which may include non-specific binding); wherein the “other enzymes” comprise a peroxidase such as HRP; and further comprise an enzyme capable of producing hydrogen peroxide (such as glucose oxidase; see example 1 and 2). The limitations of claim 41 (see also the 112-second rejection above), 43 and 44 are met by the referenced invention of Horwath as he discloses the method of screening extracellular enzymes such as glucoamylase producing host cells, wherein the other enzymes further comprise glucose oxidase. Since, all the method steps (i.e. cultivating a host cell expressing the enzyme of interest such as glucoamylase, and measuring the color of second dye) and the specific components as recited in instant claims are disclosed and explicitly taught by Horwath, the claimed invention is anticipated by the cited prior art.

As per MPEP 2111.01, during examination, the claims must be interpreted as broadly as their terms reasonably allow. In re American Academy of Science Tech Center, F.3d, 2004 WL 1067528 (Fed. Cir. May 13, 2004)(The USPTO uses a different standard for construing claims than that used by district courts; during examination the USPTO must give claims their broadest reasonable interpretation.). This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

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Conclusion

NO claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SATYENDRA K. SINGH whose telephone number is (571)272-8790. The examiner can normally be reached on 9-5MF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Satyendra K. Singh/
Examiner, Art Unit 1657

/Irene Marx/
Primary Examiner
Art Unit 1651